

Claims

1. A composition suitable for oral administration comprising clopidogrel in pharmaceutically acceptable salt form which composition comprises
  - a polymer coating selected from a polyvinyl acetate or a polyvinyl alcohol, and
  - a hydrophobic component comprising a hydrogenated vegetable oil, wherein the salt is selected from mesylate, hydrobromide, hydroiodide and hydrochloride, and wherein the clopidogrel is in the form of coated particles, granules or agglomerates.
2. A composition as claimed in claim 1 in form of a tablet, sachet or capsule.
3. A composition as claimed in claim 1 or claim 2 wherein the coated particles, granules or agglomerates are free of or substantially free of HPMC.
4. A process for preparing tablets comprising clopidogrel in pharmaceutically acceptable salt form which process comprises
  - a) compacting the clopidogrel with anhydrous or substantially anhydrous components so as to form aggregates,
  - b) breaking down the aggregates so as to form granules or particles,
  - c) optionally mixing the granules or particles with at least one further component, and
  - d) compacting or compressing the granules or particles thus formed into tablets,wherein the clopidogrel is used in mesylate, hydrobromide, hydroiodide, or hydrochloride form, and the process further comprises mixing a moisture scavenger with the aggregates, granules or particles.
5. A process as claimed in claim 4 further comprising addition of a hydrophobic lubricant.
6. A process as claimed in claim 4 or 5 carried out in a low- or ultra-low humidity environment.
7. A process as claimed in any one of claims 4 to 6 wherein step a) is carried out using roller compaction.
8. A process as claimed in any one of claims 4 to 7 which process further comprises a granule- or particle-coating step after step b) or step c) when present and before step d).
9. A process as claimed in claim 8 wherein the coating is carried out using a hydrophobic polymer, a hydrogenated vegetable oil or a cyclodextrin.
10. A tablet prepared by the process of any one of claims 4 to 9.
11. A tablet as claimed in claim 10 which is free of or substantially free of HPMC.